Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Ronald A. Guzman	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 1867	DATE	3/21/2002
CASE TITLE	ABBOTT LABORATORIES, et al vs. BAXTER PHARMACEUTICAL, et al		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] It is hereby ordered that defendant Baxter's motion for summary judgment [7-1] is granted. Plaintiff Abbott's motion to set a briefing schedule [30-1] filed on 7/17/01 is stricken as moot. This case is hereby terminated and all remaining pending motions stricken as moot. This is a final and appealable order. Enter Memorandum Opinion and Order.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.			
	Notices mailed by judge's staff.		MAR 22 2002	
	Notified counsel by telephone		date docketed	
x	Docketing to mail notices.		docketing deputy initials	68
x	Mail AO 450 form.			
	Copy to judge/magistrate judge.		date mailed notice	
CG	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES and CENTRAL GLASS COMPANY, LTD.,	)	
Plaintiffs;	)	
	)	**Case No. 01 C 1867**
v.	)	
	)	**Judge Ronald A. Guzman**
BAXTER PHARMACEUTICAL PRODUCTS, INC. and BAXTER HEALTHCARE CORP.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Pending is a motion for summary judgment pursuant to Fed.R.Civ.P. 56 by defendants Baxter Pharmaceutical Products, Inc. and Baxter Healthcare Corporation ("Baxter"). Defendants contend that their amended Abbreviated New Drug Application ("ANDA"), filed under the Hatch-Waxman Act for a generic sevoflurane product, does not infringe Plaintiffs' Abbott Laboratories and Central Glass Co., Ltd. ("Abbott") patent, U.S. Patent No. 5,990,176 (the "'176 patent"), either literally or under the doctrine of equivalents. Baxter argues that the claims of the '176 patent are limited to a sevoflurane product with a water content of at least about 150 parts per million (ppm). Because Baxter's generic sevoflurane product, as stated in the amended ANDA, has a water content of 130 ppm or less, it does not infringe literally or under the doctrine of equivalents. For the reasons stated below, the motion for summary judgment is granted in Baxter's favor.

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BACKGROUND FACTS

The Plaintiff, Abbott, is a Delaware corporation with its principal place of business in Abbott Park, Illinois. (Pl.s' LR 56.1(a)(3) ¶ 1.) Defendant Baxter Healthcare Corporation is a Delaware corporation with its principal place of business in Deerfield, Illinois. (*Id.* at ¶ 3.)

Sevoflurane is a fluorine-based inhalation anesthetic first developed by Baxter's scientists in the mid-1960s. Sevoflurane is given to surgery patients to breathe during surgery, to maintain general anesthesia. It is currently the market leader, accounting for more than 50 percent of the United States dollar sales of all inhalable anesthetics in 2000.

Although the original patent on sevoflurane has long since expired, Abbott Laboratories is the sole seller of sevoflurane in America due to a complicated licensing situation, which itself was subject to another lawsuit before this Court. *See Abbott Labs. v. Baxter Pharmaceutical Prods., Inc.*, No. 00-C-5939, (N.D.Ill, Guzman, J.). Sevoflurane has been the subject of numerous patents since its invention in the 1960s. One of these patents is the '176 patent, entitled "Fluoroether Compositions and Methods for Inhibiting Their Degradation in the Presence of Lewis Acids," filed on January 27, 1997. The '176 patent describes how to protect liquid sevoflurane from degradation by a class of chemicals known as "Lewis" acids, which are present in glass containers. These acids can cause sevoflurane to degrade considerably. The '176 patent teaches that to stop the degradation by the acids, one must simply add an "effective stabilizing amount" of a "Lewis acid inhibitor," one of which is water, to the sevoflurane composition. '176 Patent at Col. 4, Lines 32-37. According to the patent specification, when the composition is sevoflurane and the inhibitor used is water, "the amount of water employed to stabilize the composition is believed to be from about 0.0150% w/w to about 0.14% w/w (saturation level)." *Id.* at Col. 4, Lines 45-47. This would translate into from about 150 parts per

million (ppm) to about 1400 ppm. The preferred Lewis acid inhibitor is water, and the preferred amount of water is between 400 and 800 ppm. *Id.* at Col. 4, Lines 53-60. In June of 2000, Baxter filed an ANDA requesting permission from the U.S. Food and Drug Administration ("FDA") to sell a generic version of sevoflurane in competition with Abbott. Plaintiffs responded by filing suit against Baxter on two patents, the '176 patent and U.S. Patent No. 6,074,668 (the "'668 patent"). In response, Baxter filed an amended ANDA on January 26, 2001, revising its product specification in an attempt to eliminate a dispute about infringement of the two asserted patents.

Plaintiffs responded by filing a second lawsuit, the present action. The present action is a claim based solely on the '176 patent. This case arises from the fact that under the Hatch-Waxman Act, the FDA cannot approve Baxter's generic sevoflurane product until either this Court enters judgment for Baxter, or 30 months after January 2, 2001 (when Abbott received notice from Baxter that, in Baxter's view, the Baxter generic sevoflurane product did not infringe the '176 patent), whichever is first. *See* 21 U.S. C. § 355 (j)(5)(B)(iii); *Bayer AG v. Elan Pharmaceutical Research Corp.*. 212 F.3d 1241, 1244-45 (Fed. Cir. 2000). Specifically, Plaintiffs allege that Baxter's filing of a paragraph IV certificaiton with the FDA constitutes an act of infringement of the '176 patent. (Def.s' LR 56.1(b)(3)(A) ¶ 4.)

DISCUSSION

Summary Judgement Standard

Summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a

matter of law." Fed.R. Civ. P. 56(c); *Celotex Corporation v. Catrett,* 477 U.S. 317, 323 (1986). When reviewing the record on summary judgment, the court must draw all reasonable inferences in the light most favorable to the non-moving party. *Hill v. Burrell Communications Group, Inc.,* 67 F.3d 665, 667 (7th Cir.1995). To avert summary judgment, however, the plaintiff "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.,* 475 U.S. 574, 586 (1986). A dispute about a material fact is genuine only if the evidence presented is such that a reasonable jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249 (1986). If no reasonable jury could find for the party opposing the motion, it must be granted. *Hedberg v. Indiana Bell Tel. Co.,* 47 F.3d 928, 931 (7th Cir.1995).

Literal Infringement

There are two steps to a patent infringement analysis: the construction of the claims and a determination of whether the accused product or method infringes the constructed claims. *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "Claim construction is a matter of law, while infringement is a question of fact." *Abbott Lab. v. Torpharm, Inc.*, No. 97 C 7515, 2001 WL 315343, at *2 (N.D. Ill. March 30, 2001). Factual questions of infringement are frequently resolved by the district court's construction of the claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 989 (Fed. Cir. 1995) (*en banc*) (Mayer, J., concurring) ("to decide what the claims mean is nearly always to decide the case."). The Court turns first to the questions of law, the claim construction of the '176 patent.

A. Claim Construction

Independent claims 1, 6, 9 and 10 of the '176 patent speak of adding an amount of water to sevoflurane in an amount "effective" or "sufficient" to prevent degradation of the sevoflurane by a Lewis acid, such as that found in water. Only dependent claims 3 and 8 state that a numerical range of Lewis acid inhibitor is "at least about" or "about" 400 parts per million (ppm) to "about" 1400 ppm. However, generally, "limitations stated in dependent claims are not to be read into the independent claim from which they depend." *Karlin Tech, Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 972 (Fed. Cir. 1999).

Therefore, the parties dispute the meaning of the term "effective" or "sufficient" amount. Specifically, because Baxter's product will contain no more than 130 ppm of water, Baxter argues that "effective" or "sufficient" amount should not be construed to reach as far down as 130 ppm. Baxter cites two main sources of information to support this argument: the specifications of the patent, which suggest that an effective amount is "believed to be from about 0.0150% w/w to about 0.14% w/w," and the prosecution history of the patent, which reveals that Abbot made a sale of sevoflurane with a water content of 131 ppm more than one year prior to filing for the '176 patent.

In interpreting a claim, "the court should first look to the intrinsic evidence of record," the claims, the specification and the prosecution history. *Vitronics*, 90 F.3d at 582. Intrinsic evidence is the most important source of the meaning of disputed claims. *Id.* "[E]xtrinsic evidence may not be relied upon during claim construction when the intrinsic evidence is sufficient to construe the claim." *Sextant Avionique, S.A. v. Analog Devices, Inc.*, 172 F.3d 817, 826 (Fed. Cir. 1999) (citing *Bell & Howell Document Mgmt Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997)). However, it is proper for the court to look to extrinsic evidence to

interpret the patent if the public record is ambiguous in describing the scope of the patented invention. *Markman,* 52 F.3d at 978-79.

The court must first look to the claims "to define the scope of the patent invention." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995). "A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). "A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention." *Hoechst Celanese Corp. v. BP Chemns. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996). However, words of a claim are given their ordinary and customary meaning unless the patentee has chosen to be his own lexicographer. *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995). If the patentee has chosen to be his own lexicographer, "the special definition of the term" must be "clearly stated in the patent specification or file history." *Id.*

Baxter argues that the specifications of the patent, stating that an effective amount is "believed to be from about 0.0150% w/w to about 0.14% w/w," limits the terms "effective" or "sufficient" amounts in the claims, essentially that Abbot acted as its own lexicographer. The specification in the "Summary of the Invention" states that the lower numerical range of effective stabilizing amount of Lewis acid inhibitor, that "can be used is" or "is believed to be" "about 0.150% w/w" (150 ppm). '176 Patent at Col 4, Lines 31-34, 45-47 and 56-58. However, it is difficult to construe the exact meaning of "about 0.0150% w/w." The examples in the specification show that the effective amount of Lewis acid inhibitor, namely water, will be dependent on the temperature and that the higher the temperature, the more water is needed to

prevent the degradation of the sevoflurane. One example states that the degradation of the sevoflurane stopped when water was added at 1300 ppm at a temperature of 195° C for three hours. The lowest range at which the examples showed the degradation was inhibited was that of water levels higher than 206 ppm, at 40° C for 200 hours. However, no examples are given at room temperature (around 20° C) or cooler. Thus, there is nothing in the specifications to suggest that at lower temperatures, 150 ppm of water or less would not be effective to prevent degradation.

In addition, the specification states that "[t]he composition of the present invention contains a total of from about 98% w/w to about 100% w/w" sevoflurane. '176 Patent, Col. 4, Lines 1-2, 12-14. Since the composition at issue is sevoflurane and the Lewis acid inhibitor water, this could be read as stating that the amount of water required is from about 0% to 2%, which would be a range of about 0 ppm to 20,000 ppm. 130 ppm, the amount of water in Baxter's proposed product, is certainly much closer to 0 than to 20,000, as is 1300, the amount used in one of the examples. There is nothing to suggest that the "about 100% w/w" of sevoflurane referred to in the patent could not refer to sevoflurane with 130 ppm of water (99.987% sevoflurane). Therefore, nothing in the specifications inherently requires the amount of water to be 150 ppm or more.

The court would be prepared to decline to limit its interpretation of the terms "effective" or "sufficient" amount to 150 ppm or greater but for Baxter's second argument, that the prosecution history of the '176 patent shows a prior sale which must limit the claims of the patent, lest it be invalid under 35 U.S.C. § 102(b).

On July 29, 1998, during the prosecution of the '176 patent, Abbott filed an Information Disclosure Statement with the U.S. Patent Office. (Def.'s LR 56.1(a)(3) ¶ 10.) As part of this

statement, Abbott submitted a document entitled "Sevoflurane Water Content." (*Id.* at ¶ 11.) It listed the water content of each lot of sevoflurane distributed by Abbott prior to the filing date of the application for the '176 patent. (*Id.*) The first lot of Abbott sevoflurane listed on the chart, Lot No. 3298DK, had a water content of 131 parts per million. (*Id.* at ¶ 13.) This lot was manufactured on March 4, 1995. (*Id.* at ¶ 14.) More than one year prior to January 27, 1997, the filing date of the '176 patent, Abbott sold bottles of sevoflurane from Lot No. 3298DK to hospitals in the United States. (*Id.* at ¶ 15.) For example, forty-eight bottles from Lot No. 3298DK were sold on August 4, 1995 to Arlington Memorial Hospital in Arlington, Texas. (*Id.* at ¶ 16.) At least forty-eight bottles from Lot No. 3298DK were sold on or about August 17, 1995 to St. Francis Hospital in Tulsa, Oklahoma. (*Id.* at ¶ 17.) Forty-eight bottles from this lot were also sold on August 19, 1995 to St. John's Medical Center in Tulsa, Oklahoma. (*Id.* at ¶ 18.) Abbott denies selling these lots in anything other than glass containers. (Pl.'s LR 56.1(b)(3)(A) ¶ 15-18.)

Baxter's January 26, 2001 amendment to its ANDA states that Baxter's sevoflurane stored in aluminum containers will have not more than 130 PPM of water. (Def.'s LR 56.1(a)(3) ¶ 19.) The revised ANDA states "[t]he limit for Water Content for sevoflurane to be *packaged in the alternate aluminum container/closure system* is NMT 0.013% (NMT 130 ppm)." These facts are all admitted by both sides and do not require resolution at trial.

Baxter's argument is commonly used by defendants in patent infringement cases. While not asking this Court to declare the '176 patent invalid because of anticipation pursuant to 35 U.S.C. § 102(b), Baxter argues that if the patent were construed to encompass its product with a water content of 130 ppm, then such an interpretation would render the patent open to an anticipation claim, because a product containing sevoflurane with a water content of 131 ppm

was on sale more than one year prior to the filing of the '176 patent. If the '176 patent is construed to encompass such an invention, then it is manifestly invalid under 102(b). Hence, the argument goes, the patent should be construed so as to preserve its validity, and, thus, should not encompass sevoflurane with a water content of 131 ppm or less. We agree.

The court "may consider the prosecution history of the patent, if in evidence." *Vitronics*, 90 F.3d at 1582, to interpret patent claims. The prosecution history is a complete record of the entire "proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." *Id.* "The prosecution history limits the interpretation of the claim terms so as to exclude any interpretation that was disclaimed during prosecution." *Id.* at 1583. An analysis of the prosecution history may include "an examination of the prior art cited therein." *Id.* The prior art cited in the prosecution history provides "clues as to what the claims do not cover." *Id.*

If possible, claims "are generally construed so as to sustain their validity". *Whittaker Corp. v. UNR Industries, Inc.*, 911 F.2d 709, 712 (Fed. Cir. 1990). "However, when the claim's language embraces the prior art, the court is not unlimited in the extent to which it can interpret the claims." *Karsten Manufacturing Corp. v. Cleveland Gold Co.*, 242 F.3d 1376, 1384 (Fed Cir. 2001) (pointing out the difficulty of balancing a patentee's argument that a claim should be read broadly and the alleged infringer's argument that if the claims are read so broadly that they 'reach the accused device, the claims also read on the prior art and are invalid.")

"A person shall be entitled to a patent unless-- (b) the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. 102(b). "A single sale . . . is enough to bar patentability." *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 830 (Fed. Cir. 1991). Here, the parties admit that sevoflurane

with 131 ppm of water was sold in the United States more than one year prior to January 27, 1997, the date of filing of the '176 patent.

Abbott admits it made the prior sales of sevoflurance and water, with the water content of 131 ppm and less. However, Abbott argues that since the patent examiner knew of the prior sales and required no amendments because of those sales, and Abbott made no amendments because of the prior sales, it did not relinquish or disavow compositions with 131 ppm of water or less. Abbott cites to *York Products, Inc. v. Central Tractor Farm & Family Center*, 99 F.3d 1568 (Fed. Cir. 1996) for the proposition that disavowal and relinquishment of coverage of patent claims "arises as a result of amendment to overcome patentability rejections or as a result of argument to secure allowance of a claim." Nevertheless, that the examiner did not consider the prior sales invalidating does not mean that they are not such. The Court must still adhere to the rule expressed in *Whitaker* and many other cases that patent claims should, when possible, be read to preserve their validity.

Abbot also attempts to distinguish its prior sale from Baxter's proposed product by pointing out that the prior sales all involved sevoflurane in *glass* containers, while Baxter's product will be in an *aluminum* container. Because different containers may produce different amounts of Lewis acids, Abbot argues, different containers might require different amounts of water and, therefore, Abbot's prior sale would not be covered by the '176 patent, while Baxter's proposed product would be. Besides the fact that the Court can find no mention in the '176 patent that the type of container would make a difference, even assuming that Abbot's assertion were correct, there is still nothing in the '176 patent to suggest (as Abbot so aggressively asserts in response to Baxter's first argument) that 130 ppm would not be covered by the patent, regardless of the container. There is nothing to suggest that 130 ppm of water could never be

effective with a glass container. Indeed, the patent clearly teaches that lower temperatures require lower amounts of water to stabilize the compound.

Therefore, because of the prior sales of the sevoflurane and water, if the Court holds that the amount of a Lewis Acid inhibitor required to prevent degradation is as low as 131 ppm, the patent would most likely be invalid. While the Court has grave concerns about the validity of the '176 patent in light of these prior sales, and is perplexed as to the patent examiner's allowance of the claims given that information, the Court is also unwilling to declare a patent invalid without being asked to do so. Moreover, the "clear and convincing" evidence required to invalidate a patent has not yet been shown here, although the patent's invalidity has been shown to be quite probable.

The only way to maintain the validity of the '176 patent, then, would be to interpret the terms "sufficient" or "effective" amount as requiring at least 131 ppm of water. Therefore, we hold that Abbott disavowed water limits of 131 ppm or less by disclosing the prior sales of sevoflurane and water that were made more than one year before the patent was filed. The "effective amount" of Lewis acid inhibitor that is covered by "about 0.0150% w/w" does not reach 131 ppm or lower. However, we decline to delineate any more specific boundaries for "about 0.150%," as this term could be narrowed further only through additional evidence not currently in the record.

B. Comparison of Accused Product and Constructed Claim Terms

"Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s)." *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). "If any claim limitation is absent from the accused device, there is

no literal infringement as a matter of law." *Id.*

The proper analysis in an infringement action regarding an ANDA is to compare the ANDA and the documents submitted with it. *Abbott Laboratories v. Torpharm, Inc.*, 156 F.Supp.2d 738, 744 (N.D. Ill. 2001) (citing *Bayer*, 212 F.3d at 1247-50). An "ANDA applicant is bound by its ANDA submissions, and is subject to civil and criminal sanctions if it fails to comply with ANDA procedures and requirements. If the ANDA directly addresses the issue of infringement, the court should look no further, and simply compare the ANDA to the patent claims." *Id.* The Court should only compare a "biobatch," that is a sample of the proposed drug, and the patent claims if the comparison with the ANDA does not resolve the infringement. *Id.*; *see also Bayer,* 212 F.3d at 1248 (holding the hypothetical inquiry of "what the ANDA applicant will likely market if its application is approved ... is properly grounded in the ANDA application and the extensive materials typically submitted in its support.")

Baxter's January 26, 2001 amendment to its ANDA states that "[t]he limit for Water Content for sevoflurane to be *packaged in the alternate aluminum container/closure system* is NMT 0.013% (not more than 130 ppm). (Def.s' LR 56.1(a)(3) ¶ 19.) The Court has construed the "effective amount" of Lewis acid inhibitor not to reach as far as 131 ppm. Therefore, the amended ANDA does not literally infringe the '176 patent.

Doctrine of Equivalents

In its second theory of infringement Abbott relies on the doctrine of equivalents. Baxter argues that its product cannot infringe under the doctrine of equivalents, because the prior art is a limit on the possible range of equivalents. *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677 (Fed. Cir. 1990).

The doctrine of equivalents cannot expand a patent to make claims that could not have been made at the time of patent prosecution. *Id.* at 684. In this case, the Court has held that a sevoflurane product with 131 ppm of water or less could not have been covered by the original patent because of the prior sale. If such coverage could not have been obtained at the time of prosecution, then it cannot be obtained by equivalents.

Baxter also claims prosecution history estoppel under *Festo v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 563 (Fed. Cir. 2000) (en banc). Because we find that the doctrine of equivalents does not apply in this case because of *Wilson Sporting Goods*, and because *Festo* is currently under consideration by the Supreme Court, we decline to address Baxter's prosecution history estoppel argument at this time.

Therefore, Baxter's sevoflurane product, with a water content of 130 ppm, does not infringe under the doctrine of equivalents.

CONCLUSION

For the above reasons, defendant Baxter's motion for summary judgment is Granted. (#7-1). Abbott's motion to set a briefing schedule filed on 7/17/01 is stricken as moot (#30-1). This case is hereby terminated and all remaining pending motions stricken as moot. This is a final and appealable order.

SO ORDERED

ENTERED:

Ronald A. Guzman

HON. RONALD A. GUZMAN
United States Judge

3/21/02